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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/536,735	GAUCH ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,37-56,58-75,77-95,112-116 and 121-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,37-56,58-75,77-95,112-116 and 121-124* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634, and has been assigned to Primary Examiner Bradley L. Sisson.

Claim Objections

2. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Amended claim 1 now recites a limitation that the material is to flow through he membrane, which is the essential aspect of claim 2. It is not clear how claim 2 further limits amended claim 1 from which it depends. In the event that applicant elects to cancel claim 2, attention is directed to clam 3, which depends, in the alternative, from claim 2.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-56, 58-75, 77-95, and 112-124 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. Applicant in their response of 20 December 2001 direct attention to the aspect that the claimed invention is directed to a method whereby nucleic acids are first immobilized on a membrane and are subsequently passed through the membrane so to be collected. While claim 1, and claims that depend therefrom, are directed to a "process for the isolation of nucleic acids from a sample" wherein they are first immobilized on a membrane, such is not a limitation of independent claims 9, 14, 77, and 112, and claims that depend therefrom. Attention is directed to claims 9 and 14, as being exemplary of the other method claims where the nucleic acids are simply immobilized on a "non-siliceous surface." While this "non-siliceous surface could be that of a membrane (claim 66 and claims 67-72, 123 and 124 that depend therefrom), and indeed the claims do encompass such, not all of the claims are necessarily limited to "non-siliceous" surfaces that are membranes, but fairly encompass any and all non-siliceous surfaces. Claims 10-13, 20, 37-56, 58-72, 75, 76, and 121-124 depend from claim 9; claims 15-20, 37-56, 58-72, 75, 76, and 121-124 depend from claim 14; claims 78-95 depend from claim 77; and claims 113-116 depend from claim 112. In the case of claims 77-95, it is noted with particularity that while a membrane is required, it need not perform in a flow-through manner. And in claims 112-116, only claim 113 requires a membrane and then it does not have to perform in a flow-through manner. The point being, that applicant is in effect arguing limitations that are not present in all of the claims. While the claims are read in light of the specification, limitations found therein are not necessarily read into the claims. But rather, the claims are read a broadly as is reasonably possible.

6. Claim 1 and claims 2-8, 20, 38-56, 58-65, 73, 74, 121, and 122 which depend therefrom, require the isolation of nucleic acids from a sample wherein they are first bound, either directly or indirectly, to a non-siliceous membrane wherein said membrane is comprised of material selected from the group consisting of nylon, polysulfone, polyethersulfone, polycarbonate, polyacrylate, acrylic copolymer, polyurethane, polyamide, polyvinylchloride, polyfluorocarbonate, poly-tetrafluoroethylene, polyvinylidene fluoride, polyethylene-tetrafluoro-ethylene-copolymerisate, polybenzimidazole, polyethylene-chlorotrifluoro-ethylene-copolymerisate, polyimide, polyphenylene sulfide, cellulose, cellulose-mix ester, cellulose nitrate, cellulose acetate, polyacrylnitrile, polyacrylnitril-copolymer, nitrocellulose, polypropylene, and polyester. The method, as presently claimed, can be performed under virtually any temperature, with any pore size, or even no pores being present in the membrane, with gravity feed or under pressure; with virtually any releasing agent or agents being used, and where washing or no washing step is performed.

7. Clearly the breadth of the claims is quite immense. While applicant is certainly entitled to claim his or her invention as broadly as they desire, the specification still must fully enable the entire scope of the claims. A review of the disclosure, however, does not support the position of full enablement. It is noted with particularity that the pore size is significant as is the application of exceptionally high gravitational forces, e.g., 20,000 g, so to ensure that the nucleic acid is caused to pass through the membranes (Examples 1-6, 9-30). While 96-well plates were used in Examples 7 and 8, it is noted that the manner of elution employed was still that set forth in Example 1. In the method of Examples 31-35, pages 63-66, it is seen that the nucleic acid is precipitated in solution and subsequently brought into contact with the surface of the membrane

with is either 0.45 μm, or several layers of a 0.65 μm membrane, the application of pressure causing the fluid to pass through the membrane leaving the nucleic acid on its surface. The DNA is washed with 70% ethanol, and then redissolved by the addition of a low salt buffer and the addition of a vacuum or positive pressure, depending upon the side of its application.

8. In the prior Office action attention was directed to claims 51, 57, 58, and 72 as disclosing limitations that were not enabled by the specification; see page 3 of the Office action mailed 20 June 2001. While applicant has canceled 57, effectively rendering moot this issue as it relates to claim 57, applicant has provided argument at page 7 of their response of 20 December 2001, hereinafter the response, wherein attention is directed to specific locations of the specification (page 17, lines 7-29, and Example 1-31) as providing ample guidance for the effective enablement of claims 51 and 72.

9. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection as the passages directed to by applicant are found to contain limitations not recited in the claims. It is noted that page 17 of the disclosure sets forth certain concentration ranges, however, the claims are not co limited. Accordingly, the claims fairly encompass ranges of concentrations and reaction parameters far outside that of applicant's preferred embodiments. While applicant is not necessarily required to limit the claims to only the preferred embodiments, the full scope of the claims does still need to be enabled by the disclosure. At best applicant's argument may be more convincing if the claims were more inline with the disclosure, however, such is not the case before the Office and as such, the rejection is maintained against these claims. It is also noted that claim 14, like claim 58, recites the use of phenols and polyphenols, any alkali earth metals, hydroxy-functional compounds (e.g., aldite of

now-cancelled claim 57) as well as many additional compounds and compositions. The specification has not been found to enable the use of all of the various compounds and compositions enumerated in claim 14, be they singly or in combination with each and every other member as stipulated in said claim; see line 11 wherein is stated "or combination thereof".

10. It is further noted that claim 75, which depends from claim 14, defines the pore size as ranging from 0.001 micron (10 Angstroms) to 50 micrometers. A review of the disclosure fails to find enablement for this range. Indeed it is most doubtful that uniform pore size of but 10 Angstroms could be manufactured, much less reproducibly used in the claimed method whereby useful nucleic acid would be obtained. Likewise the use of a membrane of 50 μm is seemingly sufficiently large that little retention would be effected sans special precautions being taken- precautions now recited in the claims nor found in the disclosure. The specification has been found to enable the use of membranes that range in pore size from 0.45 μm to 3.0 μm (Example 29).

11. A review of the disclosure does find evidence of applicant having put forth a considerable degree of effort in comparing any number of membranes, however, the variety of membranes were compared under a significantly less broad set of conditions. Applicant is urged to consider narrowing the claims such that they are more in line with the description. In support of this position, it is note that Examples 1, 7, and 31 are pivotal. Applicant is urged to consider incorporating limitations of these three examples into a set of perhaps three parallel claim sets.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 112-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claims 112-116 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: those that are required to allow for the isolation of nucleic acids when using any of the specified materials. At present, the claims do not recite any positive method steps.

15. Claims 112-116 provides for the use of "said material", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

16. Claims 112-116 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App.1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

18. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

19. Claims 14-20, 37-50, 54-55, 59-65, 76, 112, 115, 116, 121, and 122 are rejected under 35 U.S.C. 102(e) as being anticipated by Walter et al.

20. Walter et al., disclose a device and related method of use whereby nucleic acids material is isolated. Column 5 discloses the device as being comprised of a fleece material. In figure 1 it is apparent that the fleece material, (7) extends across the diameter of the device. The sample applied to the device is first subjected to at least one method step prior to being applied to the device. The preprocessing includes the mixing of the sample with a series of buffers. At least one of the buffers comprises the chaotropic agent guanidinium HCl and potassium acetate. Once the sample is applied to the device, it is passed through the column or web of fleece as a result of centrifugation. The nucleic acids are precipitated out onto the fleece and are subjected to ethanol precipitation as a buffer of guanidinium HCl and ethanol is passed through the fleece web. The reversibly immobilized nucleic acid is eluted/released by the addition of an aqueous buffer- TE (column 9, fourth paragraph).

Response to argument

21. At page 10 of the response it is asserted that Walters et al., does not anticipate the claimed invention, as it does not disclose the temperature limitation of claim 9. This argument has been fully considered and has been found persuasive towards claim 9 and claims 10-13 that depend from said claim 9. The temperature limitation of claim 9, however, is not found in the remaining claims and as such applicant's argument has not been found persuasive towards the withdrawal of the rejection as it relates to claims 14-20, 37-50, 54-55, 59-65, 76, 112, 115, 116, 121, and 122.

22. Claims 14-20, 37-42, 46-49, 54-56, 59-65, 112, 114, 121, and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofstetter et al.

23. Hofstetter et al., columns 19-20, disclose the isolation of mRNA on a column of oligo-dT cellulose. As seen therein, the cell sample is first subjected to lysis by the use of the chaotropic agent, guanidinium thiocyanate with beta-mercaptoethanol. The sample is applied to the flow-through column whereby the mRNA is non-covalently bound to the oligo-dT molecules located on the surface of the substrate. The RNA is subjected to a salting out as a 5M NaCl buffer is applied to the column. The immobilized RNA is then subjected to wash steps where defined volumes of wash buffer are used (15 ml; column 20, first paragraph). The RNA is then eluted by the application of an aqueous elution buffer. The RNA is then subjected to air drying, followed by dissolving in TE buffer with 0.1% SDS. The resultant mRNA is analyzed by gel electrophoresis and is also used in the synthesis of cDNA (Example 8; column 22).

Response to argument

24. At page 10, last paragraph, bridging to page 11 of the response, applicant presents argument that the teachings of Hofstetter et al., to not meet the limitations of the claims invention as the claimed invention is drawn to a method which requires the reversible immobilization of nucleic acids to a non-siliceous membrane. This argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection, as applicant is arguing limitations not present in the claims.

Claims 1, 4, 6-8, 14, 16-20, 37-42, 46-49, 52, 53, 65, 73-75, 112, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Comai et al.

For purposes of examination, the claims have been interpreted as encompassing not only the above disclosed flow-though devices whereby DNA or RNA is/are isolated, but to also encompass traditional hybridization assays and the subsequent stripping of a probe from the hybridization membrane/filter.

Comai et al., column 13, first paragraph, disclose performing a traditional Southern blot whereby a nitrocellulose membrane has a capture sequence immobilized thereon and is subjected to the annealing of a complementary probe. The aspect of immobilizing the probe to the membrane is considered to meet the limitation that the membrane has been coated. Additionally, the use of a prehybridization buffer is also considered to meet this requirement. The hybridization reaction utilizes a high salt buffer (5X SSC; saline sodium citrate). Similarly, the probe is eluted or stripped off of the filter/nylon membrane through the use of a variety of buffers that also comprises SSC.

Response to argument

At pages 11-12 of the response applicant presents argument that the invention of applicant does not lie in hybridization of probes to target sequences but rather, in the reversible binding of nucleic acids to a non-siliceous membrane. This argument has been fully considered and has not been found persuasive for applicant is arguing limitations not found in the claims. As presently worded, the aspect of a nucleic acid reversibly binding to a membrane is considered to encompass direct as well as indirect immobilization. Further, the membrane used by the prior art, nitrocellulose is the very membrane contemplated by applicant; see claim 1, line 19; claim 70, line 5; claim 74, line 6; as well as claims 92 and 124.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

27. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

28. Claims 1-8, 14-20, 37-56, 58-76, 112-116, and 121-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marquet et al., in view of Mansfield et al. and Walter et al.

29. See the prior Office action for the basis of the rejection as it pertains to the disclosures of Marquet et al.

30. See above for the basis of the rejection as it pertains to the disclosure of Walter et al.

31. Marquet et al., does not disclose performing all of the steps in an automated manner but they do disclose performing certain column operations in an automated manner; see column 18, paragraph six.

32. The aspect of having the reactions take place in a nearly simultaneous manner is considered to have been met by the prior art as such would be driven by the kinetics of the assay as no special handling or features would be required.

33. Marquet et al., column 8, disclose that the membrane could be hydrophilic or hydrophobic and that one of skill in the art needs to adapt the degree of hydrophobicity such that the membrane/support/filter would still be functional.

34. Mansfield et al., column 2, disclose coating hydrophilic membranes such that they would be rendered hydrophobic. Motivation for doing such is found at column 2, penultimate paragraph where it is disclosed that they "would eliminate the need for a blocking agent and therefore would eliminate the need of a membrane wetting step to effect deposition of the blocking agent from aqueous solution."

35. Column 3, penultimate paragraph, discloses suitable membranes.

36. Column 4 discloses the use of the membranes in the isolation of nucleic acids.

37. Walter discloses a device and related method whereby nucleic acid materials are isolated. Column 5 discloses the device as being comprised of a fleece material. In Figure 1 it is apparent that the fleece material, (7) extends across the diameter of the device. The sample, which is applied to the device, is first subjected to at least one method step prior to being applied to the device. The preprocessing includes the mixing of the sample with a series of buffers. At least one of the buffers comprises guanidinium HCl and potassium acetate. Once the sample is applied to the device, it is passed through the column or web of fleece as a result of centrifugation. The nucleic acids are precipitated out onto the fleece and are subjected to ethanol precipitation as a buffer of guanidinium HCl and ethanol is passed through the fleece web. The bound nucleic acid is eluted/released by the addition of an aqueous buffer- TE (column 9, fourth paragraph).

38. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the membranes/supports/filters of Marquet et al., and to have further applied the concept of automation as disclosed in Marquet et al., for the obvious advantage of reduced method steps and reproducibility. It would have also been obvious to have modified the

methods of Marquet et al., and Mansfield et al., with that of Walter et al., as such allows for a convenient and efficient process whereby nucleic acids are isolated from a sample.

39. In view of the detailed guidance and explicit teachings of where and how method steps can be reduced or eliminated, the ordinary artisan would have both been motivated and would have had a reasonable expectation of success.

40. For the above reasons, and in the absence of convincing evidence to the contrary, the invention of claims 1-8, 14, 19, 43-45 and 66-69, 72, 77-95, 112, 113, 115, 116 and 123 is considered to be obvious in view of the prior art of record.

Response to argument

41. Applicant presents argument at pages 13-15 of the repose that (i) the rejection is based on hindsight; and (ii) that Marquet and Walter cannot be combined as such would have one attempting to bind DNA to glass fleece, an embodiment not claimed by applicant.

42. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

43. In response to applicant's argument that the use of fleece is not contemplated by applicant nor encompassed by the claims, attention is again directed to the fact that not all claims require the use of a membrane. More specifically, claim 115 requires that the "material" is "in

the form of a fiber" and that claim 116, which depends therefrom, further requires that "the fibers are organized as a fleece." Accordingly, and in spite of the emphasis of applicant argument (page 14, penultimate paragraph, of the response), applicant's argument has been found unpersuasive as they are arguing limitations not found in the claims.

44. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is applied against claims 1-8, 14-20, 37-56, 58-76, 112-116, and 121-124.

Conclusion

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

47. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

bls
March 10, 2002